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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,128	08/29/2005	Bronislava Gedulin	54061.8101.US00	7370

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EXAMINER	
LI, RUIXIANG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 07/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/518,128	GEDULIN ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-21* is/are pending in the application.

4a) Of the above claim(s) *7 and 15-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6 and 8-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on *14 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 12/14/2004, 02/28/2005, 04/03/2006, 06/01/2006
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-3 and 5-14) and an anti-inflammatory agent in the reply filed on 04/24/2006 is acknowledged. The traversal is on the ground(s) that the inventions are so linked and form a single general inventive concept and all of the pending claims are directed to a product, a PYY or PYY agonist, and a process of using the product, i.e., methods of treating an intestinal condition with a PYY or PYY agonist. Applicants further argue that the process share the general inventive concept that the PYY or PYY agonist is administered directly or indirectly to treat bowel conditions. This is not found persuasive because none of the claims are directed to a PYY or PYY agonist; instead, Invention Group I is drawn to a method of treating an intestinal damage comprising administering a pharmaceutically active formulation of PYY or a PYY agonist to a subject; whereas Invention Group II is directed to a probiotic bacterium comprising a nucleic acid encoding a PYY or PYY agonist and a method of treating a bowel condition comprising administering the bacterium to a patient. Accordingly, Groups I and II are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept. Thus, unity of invention is lacking and restriction is appropriate.

Applicants also argue that the claims of the instant invention are directed to a probiotic bacterium comprising a nucleic acid encoding PYY or a PYY agonist (a product), and methods of treating bowel conditions comprising administering PYY or

a PYY agonist (process of use). Thus, the claims have unity of invention. This is not found to be persuasive because PYY and a PYY agonist are different products from a probiotic bacterium comprising a nucleic acid encoding a PYY or PYY agonist.

Concerning the species election in claims 7 and 8, Applicants argue that under the PCT rules, there is no provision for an election of species. Applicants further argue that growth hormones and anti-inflammatory agents share a common property or activity and thus the elements of claims 7 and 8 do not lack unity of invention. This is not persuasive because an election of species may be made under PCT Rules. Moreover, according to PCT Rule 13.2, and to the guidelines in Section (f)(i)(B)(1) of Annex B of PCT Administrative Instructions, all alternatives of a Markush Group must have a common structure. Although growth hormones and anti-inflammatory agents share a common property or activity, they are not regarded as being of similar nature because they do not share a common structure.

The requirement is still deemed proper and is therefore made FINAL.

2. Applicants' preliminary amendment filed upon 08/29/2005 has been entered in full. Claims 1-3 and 5-21 are pending. Claims 1-3, 5, 6, 8-14 are currently under consideration. All other claims are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Drawings

3. The drawings filed on 12/24/2004 are accepted by the examiner.

Information Disclosure Statement

4. The information disclosure statements filed on 12/14/2004, 02/28/2005, 04/03/2006, and 06/01/2006 have been considered by the Examiner and a signed copy of form PTO-1449 is attached to the office action.

Claim Rejections—35 USC § 112, 1st paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-3, 5, 6, and 8-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

Claims 1-3, 5, 6, and 8-13 are drawn to a method of treating an intestinal damage comprising administering a pharmaceutically active formulation of PYY or a PYY agonist to a subject to treat the intestinal damage. The specification defines PYY as a peptide YY polypeptide obtained or derived from any species, and defines

PYY agonist as any compound which elicits an effect of PYY to protect from or reduce colon injury associated with inflammatory bowel disease or ulcerative colities and which binds specifically in a Y receptor assay or in a competitive binding assay (page 10). Thus, the claims are drawn to a method comprising administration of PYY or a genus of structurally undefined PYY agonists.

The specification fails to provide any critical structural feature to adequately describe the genus of PYY agonists that may be administered in the claimed method. The specification merely discloses two compounds, a human PYY of SEQ ID NO: 2 and PYY (3-36) of SEQ ID NO: 3, which are not sufficiently representative of the genus of PYY agonists. There is no defined relation between function and structure of the PYY agonists. There is even no identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the genus of PYY agonists.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of the PYY agonists, and therefore conception is not achieved until reduction to practice has occurred. Therefore, only the method of

administering PYY and PYY (3-36), but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph.

Claim Rejections—35 USC §102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3, 5, 10, and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by El-Salhy et al. (Peptides 23:397-402, February 2002).

El-Salhy et al. teach a decreased level of PYY in human patients with gastrointestinal disorders, including inflammatory bowel diseases (examples are Crohn's colitis and ulcerative colities; pages 398-399). El-Salhy et al. also teach that the changes in PYY in gastrointestinal disorders could be beneficial in clinical practice and that in cases where PYY increase is desirable, diet that increases PYY synthesis and release can be followed, or a receptor agonist can be utilized (Abstract; page 401). El-Salhy et al. further teach that infusion of PYY in dogs increases colonic absorption of water, Na and Cl ions and PYY or its analogue can be of use as clinical agents in intestinal malabsorption disorders or after bowel resection (page 401). Accordingly, the teachings of El-Salhy et al. meet the limitations of claims 1-3, 5, 10, and 13.

9. Claims 1, 2, 5, and 10-12, are rejected under 35 U.S.C. 102(b) as being anticipated by Balasubramaniam (U. S. Patent No. 5,604,203, Feb. 18, 1997).

Balasubramaniam teaches PYY and functional analogs and pharmaceutical formulations comprising PYY or an analog of PYY (column 15). Balasubramaniam also teaches treating gastrointestinal disorders, especially infectious or inflammatory diarrhea, or diarrhea resulting from surgery (column 16). Inflammatory diarrhea includes Crohn's disease (column 7), a form of inflammatory bowel disease, with PYY and its analogues (column 7). Balasubramaniam teaches that the compounds can be administered orally or parenterally (intravenously or subcutaneously) (column 14). The daily dose in the case of oral administration is typically in the range of 0.1 to 100 mg/kg body weight, and the daily dose in the case of parenteral administration is typically in the range of 0.001 to 50 mg/kg body weight (column 16). Thus, the teachings of Balasubramaniam meet the limitations of claims 1, 2, 5, and 10-12.

10. Claims 1, 10, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshinaga et al. (*Am. J. Physiol.* 263:G695-701, 1992).

Yoshinaga et al. teach a method of inhibiting pancreatic exocrine and gastric acid output comprising peripheral administration (intravenous infusion; see Experimental Design at page G696) to a subject (a mongrel dog; page G695, right column, under animal preparation) 200, 400, 800 pmol/kg/h (equivalent to about 20, 40, and 80 μg/kg/day, respectively; molecular weight of PYY=4310) of peptide YY and a PYY agonist, PYY3-36 (see, e.g., Abstract, page G696, left column, Table 3, page G697). Since Yoshinaga et al. teach a method of administering to a subject the same agent (PYY or PYY agonist, PYY3-36) via the same route of administration as

that of the instantly claimed method, the intended uses of PYY or PYY agonist recited in the claims are inherent to the method taught by Yoshinaga et al. Thus, the reference of Yoshinaga et al. meets the limitations of claims 1, 10, and 14.

Conclusion

11. No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

Ruixiang Li, Ph.D.
Primary Examiner
July 9, 2006

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PRIMARY EXAMINER